

DEC 14 2001

**510(k) Summary**  
**Orthosonix, Inc. Energex®**

K013094

**1. Sponsor**

Orthosonix  
180 Old Tappan Road  
Old Tappan, New Jersey 07675

Contact Person: Thomas Fagan  
President

**2. Device Name**

Classification Name: Shortwave diathermy device  
Proprietary Name: Orthosonix Energex®

**3. Indications for Use**

The Energex is indicated for use for the temporary relief of chronic temporomandibular joint (TMJ) pain.

**4. Device Description**

The Energex is a therapeutic medical device that delivers pulsed radio-frequency energy to tissue as indicated for the relief of chronic TMJ pain.

**5. Basis for Substantial Equivalence**

The Energex is substantially equivalent to shortwave diathermy devices that are also indicated for the relief of joint pain. This equivalence was shown through bench, animal and clinical data submitted in the 510(k).



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 14 2001

Orthosonix, Incorporated  
C/O Mr. Russell Pagano  
M Squared Associates, Incorporated  
615 7<sup>th</sup> Street Northeast  
Washington, District of Columbia 20002

Re: K013094

Trade/Device Name: Orthosonix Energex ®  
Regulation Number: 882.5890  
Regulation Name: Pulsed Radio Frequency Therapy Device  
Regulatory Class: II  
Product Code: NHH  
Dated: September 14, 2001  
Received: September 17, 2001

Dear Mr. Pagano:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

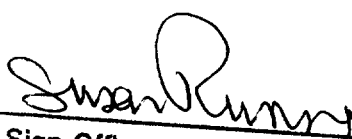
K013094

**Indication for Use Statement**

510(k) Number (if known): \_\_\_\_\_

Device Name: Orthosonix Energex®**Indication for Use:**

The Energex is indicated for use for the temporary relief of chronic temporomandibular joint (TMJ) pain.

  
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(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K013094